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UNITED STATES DISTRICT COURT

FOR THE SOUTHERN DISTRICT OF CALIFORNIA

ILLUMINA, INC. and ILLUMINA CAMBRIDGE LTD., Plaintiffs, v. COMPLETE GENOMICS, INC., Defendant.	Case No. 3:12-cv-01465 AJB BGS **DEFENDANT'S ANSWER TO COMPLAINT FOR INFRINGEMENT OF UNITED STATES PATENT NO. 8,192,930 AND COUNTERCLAIMS** **DEMAND FOR JURY TRIAL**

Defendant Complete Genomics, Inc. ("Complete Genomics"), through its undersigned counsel, hereby demands a jury trial and answers the Complaint of plaintiffs Illumina, Inc. and Illumina Cambridge Ltd. (collectively, "Illumina") as follows:

NATURE OF THE ACTION

1. Complete Genomics admits that this case purports to be an action for patent infringement under the patent laws of the United States, Title 35 U.S.C. § 100 et seq., including 35 U.S.C. § 271(a). Complete Genomics denies that it has infringed U.S. Patent No. 8,192,930 ("the '930 patent") as alleged or at all. Complete Genomics lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 1, and therefore denies them.

2. Complete Genomics denies that Illumina is entitled to any relief whatsoever from Complete Genomics or the Court, either as prayed for in the Complaint or otherwise.

THE PARTIES

3. Complete Genomics lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 3, and therefore denies them.

4. Complete Genomics lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 4, and therefore denies them.

5. Complete Genomics lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 5, and therefore denies them.

6. Complete Genomics lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 6, and therefore denies them.

7. Complete Genomics lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 7, and therefore denies them.

8. Complete Genomics admits that it is a corporation incorporated under the laws of the State of Delaware with its principal place of business at 2071 Stierlin Court, Mountain View, California, 94043.

9. Complete Genomics admits that it has been and is in the business of offering genome-sequencing services to customers throughout the United States.

JURISDICTION AND VENUE

10. Complete Genomics admits that this Court has subject matter jurisdiction over Illumina's claims, but denies that there is any basis for such claims.

11. Complete Genomics admits that this Court has personal jurisdiction over Complete Genomics.

12. Complete Genomics admits that venue is proper in this Federal District, but denies the remaining allegations of Paragraph 12.

FIRST CAUSE OF ACTION

(INFRINGEMENT BY COMPLETE GENOMICS OF U.S. PATENT NO. 8,192,930)

13. Complete Genomics repeats and realleges its answers to Paragraphs 1-12 as if fully set forth herein.

14. Complete Genomics admits that the '930 patent is entitled "Method for Sequencing a Polynucleotide Template." Complete Genomics admits that Exhibit A appears to be a copy of the '930 patent, but lacks sufficient information to verify its authenticity. Complete Genomics denies that the '930 patent was duly and legally issued. Complete Genomics admits that the '930 patent indicates on its face that it was issued on June 5, 2012.

15. Complete Genomics admits that the '930 patent indicates on its face that it claims priority to U.S. Patent Application No. 12/223,759, filed February 8, 2007.

16. Complete Genomics admits that the '930 patent indicates on its face that it was issued in the names of Eric Hans Vermaas, Graham John Worsley, Jonathan Mark Boutell, Colin Lloyd Barnes, Roberto Rigatti, Niall Anthony Gormley, Geoffrey Paul Smith, Vincent Peter Smith, Tobias William Barr Ost, and David Bentley.

17. Complete Genomics lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 17, and therefore denies them.

18. Complete Genomics denies the allegations of Paragraph 18.

19. Complete Genomics admits that Claim 1 of the '930 patent reads: "A method for pairwise sequencing of first and second regions of a double stranded polynucleotide wherein said first and second regions are in the same target double stranded polynucleotide, the method

comprising hybridising and reading from a first primer, removing the first primer followed by hybridising and reading from a second primer at a different location in the same target double stranded polynucleotide."

20. Complete Genomics lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 20, and therefore denies them.

21. Complete Genomics admits that it has been and is making, using, and selling, and/or offering for sale products, services, methods, and/or systems under the moniker "Complete Genomics Analysis Platform" or "CGA Platform."

22. Complete Genomics admits that as part of the "Complete Genomics Analysis Platform" services offered and sold to customers in the United States, Complete Genomics has been practicing and continues to practice a method referred to as "Combinatorial Probe-Anchor Ligation" or "cPAL™" read technology. Complete Genomics denies the remaining allegations of Paragraph 22.

23. Complete Genomics denies the allegations of Paragraph 23.

24. Complete Genomics denies the allegations of Paragraph 24.

25. Complete Genomics denies the allegations of Paragraph 25.

26. Complete Genomics denies the allegations of Paragraph 26.

27. Complete Genomics denies the allegations of Paragraph 27.

28. Complete Genomics denies the allegations of Paragraph 28.

PRAYER FOR RELIEF

A. Complete Genomics denies that Illumina is entitled to any relief whatsoever from Complete Genomics or the Court, either as prayed for in the Complaint or otherwise.

B. Complete Genomics further denies each and every allegation in Illumina's Complaint that is not specifically admitted, denied, or otherwise responded to in this Answer and Counterclaims.

DEFENSES

29. Complete Genomics alleges and asserts the following defenses in response to the allegations in Illumina's Complaint, undertaking the burden of proof only as to those defenses deemed affirmative defenses by law, regardless of how such defenses are denominated herein:

First Defense (Non-Infringement)

30. Complete Genomics has not infringed and does not infringe, directly, contributorily, by inducement, or in any other manner any valid or enforceable claim of the '930 patent.

31. Complete Genomics does not perform the steps of the method claims of the '930 patent.

32. It is well known that Complete Genomics utilizes single-stranded DNA templates in its sequencing methods. Illumina and its counsel are aware, based on publicly available documents, as well as documents procured during Illumina's other lawsuit against Complete Genomics, that Complete Genomics does not use a target double-stranded polynucleotide as required by the claims of the '930 patent. Rather, Complete Genomics utilizes "DNA nanoballs" which are single-stranded DNA molecules.

33. To the extent that Illumina takes the position that double-stranded DNA also means single-stranded DNA, Complete Genomics still does not infringe any valid claim of the '930 patent.

34. It is well known that Complete Genomics does not utilize a method that requires the successive incorporation of nucleotides into a polynucleotide chain. Instead, as is known by Illumina and its counsel from publicly available documents and documents obtained during the course of the other litigation between Complete Genomics and Illumina, Complete Genomics utilizes a sequencing by ligation methodology, which relies upon a hybridization and ligation process. Complete Genomics' "cPAL" technology does not rely upon the successive incorporation of nucleotides.

Second Defense (Invalidity/Unenforceability)

35. Each and every claim of the '930 patent is invalid and/or unenforceable for failure to meet the requirements of the Patent Laws of the United States, including, without limitation, one or more of 35 U.S.C. §§ 101, 102, 103, 112.

36. The claims of the '930 patent are invalid as anticipated and/or rendered obvious by at least the following prior art: Shendure, et al., Accurate Multiplex Polony Sequencing of an Evolved Bacterial Genome, Science, 309:1728-1732 (2005); U.S. Patent No. 7,960,104; U.S. Patent No. 7,906,285; U.S. Patent No. 7,910,304; and U.S. Patent No. 8,105,771, attached hereto as Exhibits 1-5, respectively. This prior art, alone or in combinations, teaches each and every element of every claim of the '930 patent.

37. The claims of the '930 patent unequivocally require that a double-stranded template be utilized. Claim 1 of the '930 patent states three times that the template must be double-stranded. *See* Dkt. No. 1, Exhibit A at col. 37, ll. 37-43; *see also id.* at Abstract (confirming that the '930 patent requires "a double-stranded polynucleotide template" in order to practice the alleged invention).

38. When describing the method of "paired-end" or "pairwise" sequencing, the '930 patent states that a double-stranded template is required because sequencing "reads" are performed on "a single polynucleotide duplex." *Id.* at col. 2, ll. 5-7. The patent states that the invention is different from the prior art because "if it is desired to sequence two regions on complementary strands of a double-stranded nucleic acid template, then it is necessary to hybridise primers to both complementary strands of the template in a single hybridisation step. Since both strands of the template remain intact and attached to the solid support . . . ." *Id.* at col. 2, ll. 55-60.

39. The first sentence of the Detailed Description of the Invention reads "[t]he invention provides methods for sequencing two regions of a target double-stranded polynucleotide template . . . [t]he first and second regions for sequence determination are either on the same strand, or on complementary strands, of the double-stranded polynucleotide template . . . ." *Id.* at col. 5, ll. 51-54. The patent refers to "polynucleotide duplexes immobilised on a

solid support . . . ." *Id*. at col. 5, ll. 59-61; s*ee also id*. at col. 8, l. 58 (where "[t]he immobilised duplex contain[ing] two complementary strands" is referenced). There are numerous examples where it is explicitly stated that the target template must be double-stranded. *See id*. at col. 9-10, ll. 9, 20-21 ("second strand of the duplex"), l. 26 ("double stranded polynucleotide templates," ll. 38-41 ("cutting of both strands of the duplex"); ll. 51-52 ("[c]onstruction of the double stranded polynucleotide templates").

40. To the extent that Illumina is alleging that double-stranded DNA means single-stranded DNA, then the Shendure prior art clearly anticipates the claims of the '930 patent. Shendure teaches sequencing multiple regions of a single-stranded DNA template by hybridizing a first primer, sequencing, removing the first primer, hybridizing a second primer, and sequencing. *See* Ex. 1 at 1729.

41. To the extent Illumina is alleging that the '930 patent covers sequencing by ligation, the sequencing method disclosed in the Shendure art is sequencing by ligation. *See id.*

42. To the extent that Illumina is alleging that the claims of the '930 patent cover the sequencing by ligation of single-stranded DNA templates, Complete Genomics owns art that anticipates such claims. Complete Genomics' Chief Scientific Officer, Dr. Radoje Drmanac, has received multiple patents which disclose (1) hybridizing an oligonucleotide to a single- or double-stranded template, (2) sequencing the template adjacent to the oligonucleotide by some method, (3) stripping off the first product, including the primer, (4) hybridizing the second oligonucleotide and (5) sequencing the template adjacent to the second oligonucleotide by some method. *See* Exhibits 2-5.

43. For example, Dr. Drmanac's U.S. Patent No. 7,960,104 claims priority to provisional application 60/725,116 ("the '116 application") filed on October 7, 2005, and discloses that "[e]ach cycle consist of a hybridization, wash, array imaging, and strip-off step." Attached hereto as Exhibit 6 at 7. The '116 application discloses all of the elements recited in Illumina's broad interpretation of claim 1 of the '930 patent: (1) hybridizing an oligonucleotide to a single- or double-stranded template [*id.* at 8 ("decoding probe" is "[h]ybridize[d] for predetermined time")], (2) sequencing the template adjacent to the oligonucleotide by some

method [*id.* ("Image each array")], (3) stripping off the first product, including the primer [*id.*, ("Drain chamber and replace with probe strip buffer…then heat chamber to probe stripoff temperature")], (4) hybridizing the second oligonucleotide [*id.*, ("Start next cycle with next decoding probe pool in set")] and (5) sequencing the template adjacent to the second oligonucleotide by some method [*id.* at 5 ("In a similar way the 6 bases from the right side of the 12mer can be decoded by using a fixed oligonucleotide and 5-prime labeled probes")].

44. As another example, Dr. Drmanac's U.S. Patent Nos. 7,906,285; 7,910,304; and 8,105,771, which claim priority to a PCT application published on September 10, 2004, disclose (1) hybridizing an oligonucleotide to a single- or double-stranded template [Ex. 5 at col. 12, ll. 7-8 ("the target nucleic acid can be double-stranded"); col. 16, ll. 61-66; and col. 26, ll. 28-30], (2) sequencing the template adjacent to the oligonucleotide by some method [*id.* at col. 16, l. 63 to col. 17, l. 8 ("When probes hybridize to adjacent sites on a target fragment, they are ligated together generating a fluorescence resonance energy transfer (FRET) signal"); col. 26, ll. 31-33; and col. 33, ll. 24-28], (3) stripping off the first product, including the primer [*id.* at col. 17, ll. 9-11 ("Once the signals from the first pool are detected, probes are removed and successive cycles are used to test different probe combinations"); col. 25, ll. 43-45; and col. 26, ll. 34-35 ("Wash to remove the first IPP pair")], (4) hybridizing the second oligonucleotide [*id.* at col. 17, ll. 9-11; and col. 26, ll. 34-35 ("followed by introduction of the second IPP pair")]; and (5) sequencing the template adjacent to the second oligonucleotide by some method [*id.* at col. 17, ll. 9-13; and col. 26, ll. 34-40].

Third Defense (Prosecution History Estoppel)

45. The arguments and amendments contained in the prosecution history of the '930 patent and/or its related applications estop or bar any claims for alleged infringement.

46. The prosecution history confirms that the patent requires the immobilization of double-stranded template. For example, when responding to a rejection over the Wiemann and O'Meara art, Illumina stated that "Wiemann fails to disclose . . . a sequencing read of a second region of the ***double stranded*** polynucleotide." Response to Office Action, June 6, 2011, p. 7 (emphasis added), attached hereto as Exhibit 7; *see also id.* at 10 (referring to Wiemann and

stating it failed to teach the claimed methods on a first and second double stranded polynucleotide).

47. Illumina referred to immobilized "nucleic acid strands and complimentary copies thereof." Exhibit 7 at 8. In a December 7, 2011 response to an Office Action to overcome the prior art, Illumina again stated that "[claim 1] recites the steps of hybridizing a first primer to obtain a sequencing read of a first region of a double stranded polynucleotide . . . ." Attached hereto as Exhibit 8 at 6-7.

48. Illumina distinguished the O'Meara prior art as being "immobilized oligonucleotides" when traversing various dependant claims. *Id*. at 8.

49. Based on the foregoing, Illumina acknowledged that the "template polynucleotides" must be double-stranded in order to overcome the prior art.

Fourth Defense (Laches/Prosecution Laches/Estoppel/Waiver)

50. Illumina's claims for alleged infringement are barred or limited by the doctrines of laches, prosecution laches, equitable estoppel, waiver, and/or other equitable doctrines.

Fifth Defense (Failure to Mark or Give Notice)

51. Illumina's claims for damages for alleged infringement are barred or limited due to failure to allege compliance with (and failure to comply with) the requirements of 35 U.S.C. § 287 or otherwise give Complete Genomics notice of the '930 patent. Complete Genomics had not been contacted by Illumina or its representatives regarding alleged infringement of the '930 patent prior to service of the Complaint in this action.

Sixth Defense (Adequate Remedy At Law)

52. Illumina's claims for injunctive relief are barred in light of the fact that Illumina has an adequate remedy at law.

Seventh Defense (Failure to State a Claim)

53. Illumina's claims for alleged infringement are barred or limited by failure to state a claim.

COUNTERCLAIMS OF COMPLETE GENOMICS, INC.

Defendant Complete Genomics, Inc. ("Complete Genomics"), upon knowledge as to its own acts and upon information and belief as to the actions of Plaintiffs Illumina, Inc. and Illumina Cambridge Ltd. (collectively "Illumina") and others, by its attorneys, alleges as follows:

THE PARTIES

1. Complete Genomics is a corporation incorporated and existing under the laws of the State of Delaware with its principal place of business at 2071 Stierlin Court, Mountain View, California, 94043.

2. On information and belief, plaintiff/counterclaim defendant Illumina, Inc. is a Delaware corporation with its principal place of business at 5200 Research Way, San Diego, California, 92122.

3. On information and belief, plaintiff/counterclaim defendant Illumina Cambridge Ltd. is a corporation organized under the laws of the United Kingdom with its principal place of business at Chesterford Research Park, Little Chesterford, Nr Saffron Walden, Essex CB10XL, UK.

JURISDICTION AND VENUE

4. This Court has jurisdiction over the subject matter of these Counterclaims under 28 U.S.C. §§ 1331, 1367, 1338(a), 2201, and 2202.

5. This Court has personal jurisdiction over Illumina as it has purposefully availed itself of the privilege of conducting activities within this State and District, including filing the Complaint in this action.

6. Venue is proper in this Federal District under 28 U.S.C. §§ 1391(b), (c), and 1400(b).

COUNT 1

(Declaratory Judgment Regarding Non-Infringement of United States Patent No. 8,192,930)

7. Complete Genomics repeats and realleges the allegations in counterclaim paragraphs 1-6 as if fully set forth herein.

8. An actual controversy exists between Complete Genomics and Illumina as to whether U.S. Patent No. 8,192,930 ("the '930 patent") is not infringed by Complete Genomics.

9. A judicial declaration is necessary and appropriate so that Complete Genomics may ascertain its rights as to whether it infringes the '930 patent.

10. Complete Genomics does not infringe, and has not infringed, any valid or enforceable claim of the '930 patent either directly, contributorily, or by inducement. Complete Genomics repeats and realleges its statements in Paragraphs 23-28 and 30-34 as if fully set forth herein.

COUNT 2

(Declaratory Judgment Regarding Invalidity of United States Patent No. 8,192,930)

11. Complete Genomics repeats and realleges the allegations in counterclaim paragraphs 1-10 as if fully set forth herein.

12. An actual controversy exists between Complete Genomics and Illumina as to whether the '930 patent is invalid.

13. A judicial declaration is necessary and appropriate so that Complete Genomics may ascertain its rights as to whether the '930 patent is invalid.

14. The '930 patent is invalid and/or unenforceable for failure to meet the requirements of the Patent Laws of the United States, including without limitation one or more of 35 U.S.C. §§ 101, 102, 103, and/or 112. Complete Genomics repeats and realleges its statements in Paragraphs 35-44 of the Answer as if fully set forth herein.

PRAYER FOR RELIEF

WHEREFORE, Complete Genomics prays for the entry of judgment as follows:

A. Dismissing the Complaint in its entirety, with prejudice;

B. Entering judgment in favor of Complete Genomics and against Illumina;

C. Declaring that Complete Genomics does not infringe and has not infringed, either directly, contributorily or by inducement, U.S. Patent No. 8,192,930;

D. Declaring that the claims of U.S. Patent No. 8,192,930 are invalid and/or unenforceable;

E. Declaring that Illumina's claims are limited and/or barred by the doctrines of laches, prosecution laches, estoppel and/or waiver;

F. Finding that this is an exceptional case under 35 U.S.C. § 285 and ordering Illumina to reimburse Complete Genomics for its attorneys fees and cost incurred in connection with this action; and

G. Granting Complete Genomics such other and further relief as justice and equity may require.

JURY DEMAND

Complete Genomics hereby demands a trial by jury on all issues and claims so triable.

Dated: July 9, 2012

Respectfully submitted,

KAYE SCHOLER LLP

By: */s/ Michael J. Malecek*
Michael J. Malecek
Attorneys for Defendant
COMPLETE GENOMICS, INC.